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| APPLICATION NO.                 | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|---------------------|------------------|
| 10/631,882                      | 07/31/2003  | Christian Schulz     | MASIMO.381A         | 1803             |
| 20995                           | 7590        | 10/31/2006           | EXAMINER            |                  |
| KNOBBE MARTENS OLSON & BEAR LLP |             |                      | NASSER, ROBERT L    |                  |
| 2040 MAIN STREET                |             |                      | ART UNIT            | PAPER NUMBER     |
| FOURTEENTH FLOOR                |             |                      |                     |                  |
| IRVINE, CA 92614                |             |                      | 3735                |                  |

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                              |                  |  |
|------------------------------|------------------------------|------------------|--|
| <b>Office Action Summary</b> | Application No.              | Applicant(s)     |  |
|                              | 10/631,882                   | SCHULZ ET AL.    |  |
|                              | Examiner<br>Robert L. Nasser | Art Unit<br>3735 |  |

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 18 August 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-5 and 7-27 is/are pending in the application.  
 4a) Of the above claim(s) 22-27 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-5, 7-27 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_.  
 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

Applicant's election without traverse of Group I, claims 1-5 and 7-21 in the reply filed on 8/18/2006 is acknowledged. Accordingly, claims 22-27 are withdrawn from consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Palatnik et al 6654621. Palatnik shows an oximetric clip sensor including an emitter that emits 2 wavelengths and a detector 18, a plurality of windows in the clip housing for allowing the passage of light, where the emitter and detector are in the clip housing and are moveable relative to each other, and a plurality of tissue contacting surfaces on the housing which do not contact each other when the device is not applied to a measurement site (see gap 10, in figure 2).

Claims 4, 8, 9, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuse et al 5313940. Fuse shows an oximetric finger clip assembly including a two wavelength source and detector, 9 and 10, and a clip housing mounting the detector and emitter in moveable relationship to each other, where the source and

detector are covered with a tissue contacting surface comprising silicone lens 21 and 22 and wavy material 23 and 24, where the wavy material covers a portion of the lenses.

As such, the lenses have a textured exterior surface. Claim 8 is rejected in that the lenses have "similar" properties to glass. Claim 9 is rejected in that it is a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See *In re Thorpe* 777 F.2d 695, 698, 227 USPQ 964, 966. Since the product of Fuse is a silicone lens, it meets the claim language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palatnik et al in view of Goldberger et al, US 5,676,139. As to Claim 2, Goldberger teaches a "spring probe clip housing," which has an adhesive material to prevent the movement of the patient's finger, 3, within the probe housing, 1. Column 4, Lines 25-32 Goldberger teach spring clips for housing probes used for pulse oximetry. Therefore,

it would have been obvious for one with ordinary skill in the art, at the time of the invention to modify Palatnik include adhesive tabs on ,the tissue contacting surfaces, in order to prevent movement of the sensor housing as taught by Goldberger. As to Claim 3, Goldberger-2 teaches wherein said adhesive tabs are removable.

Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuse et al in of Weckstrom et al., US 6,041,247. As to Claim 5, Weckstrom teaches pliable silicone lenses, i.e. "commercially available silicone polymers, [which] are readily moldable to a proper shape." [Column 8, Lines 19-20] As such, it would have been obvious to modify Fuse to use such a lens, as it is merely the substitution of one known equivalent lens for another. As to claim 7, 12. As to Claim 7, Weckstrom teaches, wherein at least one of said silicone lenses is sized to have a surface area greater than a surface area defined by at least one of the windows: [See FIG 3, Item 16]. As such, it would have been obvious to modify Fuse to use such a lens, as it is merely the substitution of one known equivalent lens for another.

Claims 9-12, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuse et al. With respect to claim 9, alternatively, the examiner takes official notice that it is well known in the art to fabricate silicone materials by the process injection molding. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to make the silicone lens by the process of injection molding. 15. As to Claims 10-12, applicant has not stated the exact shape of the lenses is for a specific purpose or that it solves a stated problem. As such, the exact shape would have been a mere matter of design choice for one skilled in the art. Claims 17

and 18 are rejected in that applicant has not stated the exact force is for a specific purpose or that it solves a stated problem. As such, the exact force would have been a mere matter of design choice for one skilled in the art.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palatnik in view of Gronvall 5810724. Gronvall shows a clip type oximeter with removable source and detector. As such, it would have been obvious to modify Palatnik to use such a removable source and detector, to minimize cross contamination.

Claim 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palatnik in view of Schmidt et al 5413099. In addition to the features of Palatnik discussed above, in figure 19 Schmidt further teaches using an ands attachment support 45 to make the connection more secure. As such, it would have been obvious to modify Palatnik to use such a attachment support, to ensure more accurate measurements. With respect to claim 16, the exact shape of the support would have been a mere matter of design choice for one skilled in the art.

Claim 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuse et al in of Isaacson et al 5792052. In figure 3, Isaacson shows the ridges 44, 46, 48 to enhance the grip on the device. Hence, it would have been obvious to modify Fuse to use such ridges, to enhance the grip on the device.

Applicant's arguments filed 8/18/2006 have been fully considered but they are moot in view of the new grounds of rejection. .

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser  
Primary Examiner  
Art Unit 3735

RLN  
October 27, 2006



ROBERT L. NASSER  
PRIMARY EXAMINER